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TRACKING Number: 7005 0390 0001 6443 5087

28 February 2007

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TSCA Document Control Office (7407M)
ATTN: TSCA Section 8(e) Coordinator
EPA East Building, Room 6428
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

CONTAINS NO CBI

Contains No CBI

Re: TSCA 8(e) Submission for draft Sub-chronic Toxicity data on 1,2-Diaminocyclohexane

Dear Sir:

INVISTA is submitting draft results from an OECD 422, sub-chronic toxicity study on 1,2-Diaminocyclohexane (DYTEK® DCH-99), CASRN 694-83-7, conducted by NOTOX B.V., in the Netherlands.

Gross pathology results from a 28-day toxicity study with DYTEK® DCH-99, in drinking water, revealed a pale discoloration of livers in male rats of the high dose group (500 mg/kg). Pale discoloration of the liver was noted in 5 males. No discoloration was seen in any other dose group (0, 50, 150 mg/kg). No clear effect on liver weight was noted when compared to other high dose male animals which did not show pale discoloration of the liver. However, when adjusted for body weight, an increase in liver weight was noted in all high dose males, when compared to control males. The NOEL for liver effects was 150 mg/kg.

In order to further evaluate whether the pale discoloration and/or organ weight changes are of toxicological relevance, microscopic examination and evaluation will be conducted. In the absence of microscopic information there is an indication that there may be a treatment related effect on the liver in the high dose male rats.

The above information is from a draft study that has not yet been completed. INVISTA will submit the final version of the study to EPA when it becomes available.

This report is being submitted in accordance with TSCA Section 8(e) guidance. Please do not hesitate to contact me if you have any questions. I may be reached at (316) 828-1470.

Sincerely,

Betsy Duncan

Betsy Duncan
TSCA Program Manager
Environmental Health and Safety

Attachments

8EHQ-07-16749

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MACROSCOPIC FINDINGS
MALES
ALL NECROPSIES

ANIMAL	ORGAN	FINDING	DAY OF DEATH
GROUP 1 (CONTROL)			
1		No findings noted	Scheduled necropsy, 08Feb2007
2		No findings noted	Scheduled necropsy, 08Feb2007
3		No findings noted	Scheduled necropsy, 08Feb2007
4		No findings noted	Scheduled necropsy, 08Feb2007
5	Kidneys	Right side: pelvic dilation.	Scheduled necropsy, 08Feb2007
6	Bone	Tail apex: bent.	Scheduled necropsy, 08Feb2007
7		No findings noted	Scheduled necropsy, 08Feb2007
8		No findings noted	Scheduled necropsy, 08Feb2007
9		No findings noted	Scheduled necropsy, 08Feb2007
10		No findings noted	Scheduled necropsy, 08Feb2007
GROUP 2 (50 MG/KG)			
11		No findings noted	Scheduled necropsy, 08Feb2007
12		No findings noted	Scheduled necropsy, 08Feb2007
13		No findings noted	Scheduled necropsy, 08Feb2007
14		No findings noted	Scheduled necropsy, 08Feb2007
15	Bone	Tail apex: bent.	Scheduled necropsy, 08Feb2007
16		No findings noted	Scheduled necropsy, 08Feb2007
17		No findings noted	Scheduled necropsy, 08Feb2007
18		No findings noted	Scheduled necropsy, 08Feb2007
19		No findings noted	Scheduled necropsy, 08Feb2007
20	Seminal vesicles	Right side: reduced in size.	Scheduled necropsy, 08Feb2007
GROUP 3 (150 MG/KG)			
21		No findings noted	Scheduled necropsy, 08Feb2007
22		No findings noted	Scheduled necropsy, 08Feb2007
23		No findings noted	Scheduled necropsy, 08Feb2007
24		No findings noted	Scheduled necropsy, 08Feb2007
25		No findings noted	Scheduled necropsy, 08Feb2007
26		No findings noted	Scheduled necropsy, 08Feb2007
27		No findings noted	Scheduled necropsy, 08Feb2007
28		No findings noted	Scheduled necropsy, 08Feb2007
29		No findings noted	Scheduled necropsy, 08Feb2007
30	Seminal vesicles	Left side: reduced in size.	Scheduled necropsy, 08Feb2007
GROUP 4 (500 MG/KG)			
31	Liver	Discolouration, pale.	Scheduled necropsy, 08Feb2007
32		No findings noted	Scheduled necropsy, 08Feb2007
33	Liver	Discolouration, pale.	Scheduled necropsy, 08Feb2007
34		No findings noted	Scheduled necropsy, 08Feb2007
35	Liver	Discolouration, pale.	Scheduled necropsy, 08Feb2007
36	Liver	Discolouration, pale.	Scheduled necropsy, 08Feb2007
37		No findings noted	Scheduled necropsy, 08Feb2007
38		No findings noted	Scheduled necropsy, 08Feb2007
39		No findings noted	Scheduled necropsy, 08Feb2007
40	Liver	Discolouration, pale.	Scheduled necropsy, 08Feb2007

ORGAN WEIGHTS (GRAM)
MALES
END OF TREATMENT

ANIMAL	BODY W. (GRAM)	BRAIN (GRAM)	HEART (GRAM)	LIVER (GRAM)	THYMUS (GRAM)
GROUP 1 (CONTROL)					
1	451	2.03	1.348	12.08	0.619
2	413	2.02	1.319	10.65	0.324
3	444	---	---	---	---
4	410	1.89	1.149	9.95	0.417
5	421	---	---	---	---
6	437	2.13	1.240	11 73	0.532
7	451	2.14	1.259	12.94	0.445
8	397	---	---	---	---
9	380	---	---	---	---
10	437	---	---	---	---
GROUP 2 (50 MG/KG)					
11	453	---	---	---	---
12	407	2.21	1.273	10.47	0.334
13	410	2.03	1.285	10.75	0.338
14	420	2.13	1.257	10.65	0.369
15	381	---	---	---	---
16	395	2.20	1.405	10.41	0.450
17	410	2.11	1.391	9.82	0.269
18	408	---	---	---	---
19	422	---	---	---	---
20	458	---	---	---	---
GROUP 3 (150 MG/KG)					
21	411	2.25	1.389	11.26	0.405
22	459	2.11	1.490	11.30	0.556
23	375	1.95	1.212	9.74	0.236
24	386	2.11	1.203	9.23	0.311
25	464	2.01	1.447	13.12	0.386
26	400	---	---	---	---
27	455	---	---	---	---
28	425	---	---	---	---
29	396	---	---	---	---
30	388	---	---	---	---
GROUP 4 (500 MG/KG)					
31	412	2.15	1.405	12.49	0.242
32	410	2.11	1.380	11.50	0.347
33	410	---	---	---	---
34	408	2.07	1.453	12.90	0.284
35	381	2.06	1.446	12.98	0.305
36	384	2.08	1.398	12.44	0.248
37	391	---	---	---	---
38	411	---	---	---	---
39	393	---	---	---	---
40	428	---	---	---	---

ORGAN WEIGHTS (GRAM)
MALES
END OF TREATMENT

ANIMAL	KIDNEYS (GRAM)	ADRENALS (GRAM)	SPLEEN (GRAM)	TESTES (GRAM)	EPIDIDYMIDES (GRAM)
GROUP 1 (CONTROL)					
1	3.00	0.068	1.052	3.48	1.054
2	3.29	0.070	1.096	4.51	1.448
3	---	---	---	4.10	1.357
4	2.82	0.068	0.781	3.83	1.167
5	---	---	---	4.34	1.224
6	3.17	0.046	1.219	3.92	1.181
7	3.50	0.085	1.250	4.01	1.229
8	---	---	---	4.10	1.142
9	---	---	---	3.86	1.344
10	---	---	---	4.25	1.353
GROUP 2 (50 MG/KG)					
11	---	---	---	3.66	1.351
12	3.20	0.067	0.937	4.14	1.187
13	2.93	0 073	0.938	3.79	1.150
14	2.96	0.087	0.841	3.70	1.262
15	---	---	---	3.62	1.209
16	3.00	0.058	1.086	3.60	1.290
17	3.54	0.066	0.816	3.01	1.024
18	---	---	---	3.72	1.284
19	---	---	---	3.92	1.313
20	---	---	---	3.78	1.199
GROUP 3 (150 MG/KG)					
21	2.82	0.076	1.072	3.58	1.182
22	3.63	0.064	1.084	4.18	1.248
23	2.96	0.059	0.846	3.64	1.124
24	2.88	0.079	0.889	3.49	1.163
25	3.19	0.074	1.223	4.30	1.242
26	---	---	---	3.86	1.074
27	---	---	---	3.69	1.157
28	---	---	---	3.79	1.176
29	---	---	---	4.21	1.166
30	---	---	---	3.70	1.158
GROUP 4 (500 MG/KG)					
31	3.19	0.085	0.866	3.74	1.013
32	3.13	0.082	1.013	3.99	0.909
33	---	---	---	3.97	1.058
34	3.48	0.085	0.913	4.22	1.032
35	3.09	0.076	0.835	3.58	1.021
36	2.88	0.062	0.820	3.83	0.995
37	---	---	---	3.87	0.886
38	---	---	---	4.57	1.148
39	---	---	---	3.84	1.172
40	---	---	---	4.35	1.124

ORGAN/BODY WEIGHT RATIOS (%)
MALES
END OF TREATMENT

ANIMAL	BODY W. (GRAM)	BRAIN (%)	HEART (%)	LIVER (%)	THYMUS (%)
GROUP 1 (CONTROL)					
1	451	0.45	0.299	2.68	0.137
2	413	0.49	0.319	2.58	0.078
3	444	---	---	---	---
4	410	0.46	0.280	2.43	0.102
5	421	---	---	---	---
6	437	0.49	0.284	2.68	0.122
7	451	0.47	0.279	2.87	0.099
8	397	---	---	---	---
9	380	---	---	---	---
10	437	---	---	---	---
GROUP 2 (50 MG/KG)					
11	453	---	---	---	---
12	407	0.54	0.313	2.57	0.082
13	410	0.49	0.313	2.62	0.082
14	420	0.51	0.299	2.53	0.088
15	381	---	---	---	---
16	395	0.56	0.356	2.63	0.114
17	410	0.51	0.339	2.39	0.066
18	408	---	---	---	---
19	422	---	---	---	---
20	458	---	---	---	---
GROUP 3 (150 MG/KG)					
21	411	0.55	0.338	2.74	0.099
22	459	0.46	0.325	2.46	0.121
23	375	0.52	0.323	2.60	0.063
24	386	0.55	0.312	2.39	0.081
25	464	0.43	0.312	2.83	0.083
26	400	---	---	---	---
27	455	---	---	---	---
28	425	---	---	---	---
29	396	---	---	---	---
30	388	---	---	---	---
GROUP 4 (500 MG/KG)					
31	412	0.52	0.341	3.03	0.059
32	410	0.51	0.337	2.80	0.085
33	410	---	---	---	---
34	408	0.51	0.356	3.16	0.070
35	381	0.54	0.380	3.41	0.080
36	384	0.54	0.364	3.24	0.065
37	391	---	---	---	---
38	411	---	---	---	---
39	393	---	---	---	---
40	428	---	---	---	---

ORGAN/BODY WEIGHT RATIOS (%)
MALES
END OF TREATMENT

ANIMAL	KIDNEYS (%)	ADRENALS (%)	SPLEEN (%)	TESTES (%)	EPIDIDYMIDES (%)
GROUP 1 (CONTROL)					
1	0.66	0.015	0.233	0.77	0.234
2	0.80	0.017	0.265	1.09	0.351
3	---	---	---	0.92	0 306
4	0.69	0.017	0.190	0.93	0.285
5	---	---	---	1.03	0.291
6	0.72	0.011	0.279	0.90	0.270
7	0.78	0.019	0.277	0.89	0.273
8	---	---	---	1.03	0.288
9	---	---	---	1.02	0.354
10	---	---	---	0.97	0.310
GROUP 2 (50 MG/KG)					
11	---	---	---	0.81	0.298
12	0.79	0.016	0.230	1.02	0.292
13	0.71	0.018	0.229	0.93	0.280
14	0.70	0.021	0.200	0.88	0.300
15	---	---	---	0.95	0.317
16	0.76	0.015	0.275	0.91	0.327
17	0.86	0.016	0.199	0.73	0.250
18	---	---	---	0.91	0.315
19	---	---	---	0.93	0.311
20	---	---	---	0.83	0.262
GROUP 3 (150 MG/KG)					
21	0.69	0.018	0.261	0.87	0.288
22	0.79	0.014	0.236	0.91	0.272
23	0.79	0.016	0.226	0.97	0.300
24	0.75	0.020	0.230	0.90	0.301
25	0.69	0.016	0.264	0.93	0.268
26	---	---	---	0.97	0.269
27	---	---	---	0.81	0.254
28	---	---	---	0.89	0.277
29	---	---	---	1.06	0.294
30	---	---	---	0.95	0.298
GROUP 4 (500 MG/KG)					
31	0.77	0.021	0.210	0.91	0.246
32	0.76	0.020	0.247	0.97	0.222
33	---	---	---	0.97	0.258
34	0.85	0.021	0.224	1.04	0.253
35	0.81	0.020	0.219	0.94	0.268
36	0.75	0.016	0.214	1.00	0.259
37	---	---	---	0.99	0.227
38	---	---	---	1.11	0.279
39	---	---	---	0.98	0.298
40	---	---	---	1.02	0.263

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TSCA 8(e) Substantial Risk Reporting Determination & Substantial Risk Review Committee (SRRC) Worksheet

NOTE: Every effort should be made to complete the Preliminary Review within 5 days of receipt of the substantial risk information or data, if possible. If reportable to the EPA, the report must be submitted within 30 calendar days of receipt of information or data by an INVISTA employee capable of appreciating the significance of the information.

Date Substantial Risk Information Received by INVISTA: 2/16/2007

Final Date the Notification is due to EPA (if required): 3/18/2007

PRELIMINARY REVIEW
Reviewer Name: Mark Mayes
Title: Managing Principal/Regulatory Toxicologist
Company: Experien Health Sciences, Inc.
Date Request Received: 2/16/07 **Due Date: 2/21/2007**

Substance Name: 1,2-Diaminocyclohexane (DYTEK® DCH-99)

CASRN: 694-83-7

Study Identifiers: OECD 422, DCH-99, Liver, Males, Sub-chronic

Study Date: 2006-2007, In progress

Study Type: OECD 422 28-Day Sub-chronic Toxicity Study with Repro

Summary:
Gross pathology results from a 28-day toxicity study with DYTEK® DCH-99, in drinking water, revealed a pale discoloration of livers in male rats of the high dose group (500 mg/kg). Pale discoloration of the liver was noted in 5 males. No discoloration was seen in any other dose group. No clear effect on liver weight was noted when compared to other high dose male animals which did not show pale discoloration of the liver. However, when adjusted for body weight, an increase in liver weight was noted in all high dose males, when compared to control males. NOEL for liver effects was 150 mg/kg.

To further evaluate whether the pale discoloration and/or organ weight changes are of toxicological relevance, microscopic examination and evaluation will be conducted. Unfortunately, these results are not likely to be available until late April or early May, 2007. In the absence of microscopic information there is an indication that there may be a treatment related effect on the liver in the high dose male animals.

Note: A review of the literature was conducted for this endpoint. This endpoint has not been described previously in the scientific literature, for DYTEK® DCH-99.

SRRC Review Required YES

Study Details:
Gross pathology results from a 28-day toxicity study with DYTEK® DCH-99 in drinking water indicated a pale discoloration of livers in male rats of the high dose group. Pale discoloration of the liver was noted in 5 males. No clear effect on liver weight was noted when compared other high dose male animals which did not show pale discoloration of the liver. However, when adjusted for body weight, an increase in liver weight was noted in all high dose males, when compared to control males. NOEL for liver effects was 150 mg/kg.

8(e) Reportable (Yes/No): YES
(To be decided by the SRRC committee.)
Date Due to the EPA (w/in 30 days of date received by INVISTA): 3/18/2007

8(e) Rationale:
The gross pathology findings of this sub-chronic study on DYTEK® DCH-99 may be reportable as a hazard under TSCA 8(e). Effects seen in a vital organ, the liver, may be a dose-dependent, irreversible effect. Histopathology will aid in further clarification of the seriousness of the effect. However, this microscopic analysis will not be available during the TSCA 8(e) reporting "window". It is possible that, should the Committee

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agree that this gross effect is reportable, that retraction of this finding may be necessary at a later date. No determination was made as to whether the findings of this study represent a significant risk of injury to human health.
Date of SRRC Review: 2/23/2007
Reviewed by: (*SRRC Members*) Betsy Duncan, Mia Lombardi, Heather Blankinship, John Mikan, Mark Mayes, Blake Biles

CERTIFIED MAIL™

INVISTA™

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